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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,323	03/20/2000	STEFAN SANNER	258.00040101	2155

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EXAMINER

CROSS, LATOYA I

ART UNIT PAPER NUMBER

1743

DATE MAILED: 09/09/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/446,323	SANNER, STEFAN	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

**-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 26 June 2003.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-3, 7, 8 and 10-26 is/are pending in the application.

4a) Of the above claim(s) 21 is/are withdrawn from consideration.

5) ☒ Claim(s) 13-18 and 23 is/are allowed.

6) ☒ Claim(s) 1-3, 7, 8, 10-12, 19, 20 and 22 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All   b) ☐ Some \*   c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

This Office Action is in response to Applicants' amendment filed on June 26, 2003 and entered as Paper No. 15. Claims 1-3, 7, 8 and 10-26 are pending. Claim 21 is withdrawn from consideration as being directed to non-elected subject matter.

***Specification***

1. The abstract of the disclosure is objected to because the abstract contains legal phraseology (e.g. "means"). Correction is required. See MPEP § 608.01(b). Applicants have chosen not to amend the abstract because "there is no indication that this sort of language cannot be used". In response, MPEP § 608.01(b) clearly states that such language should be avoided. Applicant's use of language such as "testing means" and "sample taking means" imposes upon the reader need to consult the full patent text to define these "means". Thus, the intended purpose of the abstract is not met. It is suggested that Applicants amend the abstract to better define the invention, without having to consult the specification.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1, 3, 8, 10-12, 19-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,534,939 to Smith et al.

Smith et al teaches a device for self-contained coagulation detection. The device comprises a housing (24) in which a cartridge (52), testing means (74) and sample taking means (102) are positioned. The cartridge contains activator reagent. The activator reagent is preferably retained substantially within an enclosure defined by an inverted cup-shaped structure (54). The activator agent (52) is thereby confined between the inverted cup-shaped structure (54) and the partition (38). The cup shaped structure (54) is glued or otherwise fastened to the interior surface of the lower portion (48) by a spot of adhesive (56). The testing means is a chamber defined by (60) and partition (38). The sample taking means comprises a syringe which, by definition, inherently includes a chamber. Additionally, the cartridge and testing means are brought into contact with the sample mixture for analyzing this mixture.

See figures 11-16.

4. Claims 1-3, 8, 11, 12, 19, 20, 22 and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,048,735 to Hessel et al.

Hessel et al teaches a multi-sectioned fluid delivery device for immunoassay detection. The device comprises a housing (6) in which a plurality of cartridges (8), testing means (1) and sample taking means (e.g. inside cap 16) are positioned. The biological sample is placed in the cap and the cap is fitted onto the distal end of the syringe portion (9). The testing means is a sensor laminate (1) and permits binding of any target molecule in the sample to the reactive substrate layer (3) of the sensor laminate. The turning handle (14) is then rotated so that the plunger (15), sensor laminate (1) and piercing element (7) move toward the distal end of the

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syringe (9) extending into the cap (16) so that the piercing element (7) sequentially pierces each divider (18) of each compartment (8) thereby displacing the compartments and releasing the fluids in an ordered sequence to detect any bound target molecules on the sensor laminate (1).

See col. 9, line 20 – col. 10, line 54; figures 4-6).

***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al or Hessel et al in view of US Patent 4,269,237 to Berger.

Smith et al and Hessel et al, as previously discussed above, teach a rupturable membrane for controlling the flow of material through the cartridge. However, neither Smith et al nor Hessel et al recite the specific use of a ball valve for closing the opening of a cartridge. The use of ball valves is considered conventional in the dispensing art, as taught by Berger. Berger teaches a device for draining or collecting sump oil from a container, wherein the container has a drain plug closed by a ball valve or rupturable membrane. See abstract.

Accordingly, it would have been obvious to one of ordinary skill in the art to have substituted the rupturable membrane means of Smith et al or Hessel et al with the ball valve, taught by Berger. Ball valves are known within the art to provide reliable sealing which can be reused repeatedly.

*Response to Arguments*

7. Applicant's arguments filed June 26, 2003 have been fully considered but they are not persuasive.

With respect to the rejection under 35 USC 102(b) over the Smith et al reference, Applicants argue that the testing means of Smith et al comprises a reagent contained in a chamber having a partition, whereas the testing means claimed by Applicant is a feature for actually examining, observing, and/or evaluating the sample mixture. It is the position of the Examiner that the reagent of Smith et al is in fact a testing means, sufficient to read on Applicants' claims. Smith et al teach at col. 5, lines 52-65 that the reagent in the chamber may be one used in titration tests, activated clotting time tests or dose response tests. Thus, the reagent is in fact a "testing means", in that it aids in evaluating the sample. Further, Applicants' claims are not limited to a testing means for "examining, observing, and/or evaluating a sample mixture". By using the phrase "testing means", the phrase is given its broadest reasonable interpretation; thus, the prior art need only teach some means capable of testing. Limitations regarding Applicants' preferred testing means cannot be read into the claims. Also, mean plus function analysis, under 35 USC 112, 6<sup>th</sup> paragraph is NOT invoked in this case because Applicants' claims do not recite "mean for", as required by MPEP 2181. Thus, the rejection over Smith et al is maintained.

With respect to the rejection under 35 USC 102(e) over the Hessel et al reference, Applicants argue, "there is no teaching in Hessel et al of the compartments 8 being displaced relative to the housing". The Examiner disagrees. At col. 9, lines 36-44 clearly states that upon entry of a gas or liquid through the nozzle (10) and valve (11) into the interior of the hollow syringe (9), resulting pressure in the interior of the syringe **slides the first and second**

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**pistons and multiple compartments (8) toward the proximal end of the hollow syringe and the piercing element.** This is a clear teaching that the compartments (8) are movable within the housing (6). Thus, the rejection over Hessel et al is maintained.

The rejection over Smith et al or Hessel et al in view of Berger is also maintained, as Applicants' arguments regarding Smith et al and Hessel et al are not persuasive.

***Allowable Subject Matter***

8. Claim 13-18 and 23 are allowed. The previous Office Action provides a statement for the reasons for the indication of allowable subject matter.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC  
September 6, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700